

ALLEGED SHIPMENT: On or about February 18, May 8, November 11 and 17, and December 9, 1950, and March 10 and 15, 1951, by Electro-Technic Products, from Chicago, Ill.

PRODUCT: 21 brown simulated leather No. 411 *Violetta kits*, each kit containing a Violetta generator, to which was attached an electric cord; a No. 1 or "General" electrode; and a leaflet entitled "Warning." In addition to the above kits, there were 35 unlabeled accessory attachments consisting of electrodes of various shapes and a number of leaflets entitled "The Advanced Violetta Kits" and "Violetta Electrodes," at Philadelphia, Pa.

The device was an electrical generator to be plugged into an electric outlet to produce a high voltage, higher frequency electrical current. The various shaped electrodes were to be used interchangeably on the generator, and consisted of hermetically sealed glass tubes, each containing a gas under low pressure.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since its labeling failed to specify the method of using the device in the treatment of conditions of the prostate, ear, spine, inside of the throat, vagina, nasal passages, urethra, rectum, and dental abscesses, and for the removal of moles, warts, and growths, which were the purposes and conditions for which the device was offered in the leaflet entitled "Violetta Electrodes" accompanying the device.

Further misbranding, Section 502 (a), the following statements in the accompanying leaflets entitled "The Advanced Violetta Kits" and "Violetta Electrodes" were false and misleading since the device was not capable of producing the effects claimed or of providing benefit in all conditions of the various organs of the body stated and implied: (Leaflet entitled "The Advanced Violetta Kits") " * * * electrical aid in treatments of the skin or the scalp * * * , " * * * provide the therapeutic values desired to aid in the correction of skin and scalp deficiencies," "It brings nourishment to the hair follicles if used as a scalp treatment or, if used for general body or facial work, the stimulating qualities of the rays carry the food values in the blood stream to feed the epidermis cells on the surface of the body," and " * * * for the treatment of many common conditions"; and (leaflet entitled "Violetta Electrodes") " * * * for any surface application," " * * * very desirable in deep-seated cases," "Used for all scalp treatments. Stimulates the hair roots and cells," "For spinal treatments," "Throat Electrode," "Special Vaginal Electrode," "Vaginal Electrode," "Prostatic Electrode," "Length just right to reach prostate gland," "Internal Throat Electrode," "Nasal and Ear Electrode," "A special Ear Electrode * * * fits in the ear passage," "Urethral Electrode," "Rectual Electrode," "Dental Electrode," and "Dental Abscess."

DISPOSITION: June 27, 1951. Default decree of condemnation and destruction.

DRUG FOR VETERINARY USE

3506. Misbranding of oil-acid-iodine. U. S. v. 29 Cases * * *. (F. D. C. No. 30908. Sample No. 25263-L.)

LIBEL FILED: On or about April 11, 1951, District of Delaware.

ALLEGED SHIPMENT: On or about March 2, 1951, by Whitmoyer Laboratories, Inc., from Myerstown, Pa.

PRODUCT: 29 cases, each containing 4 1-gallon bottles, of *oil-acid-iodine* at

Milton, Del. Examination showed that the product contained fish liver oil, hydrochloric acid, and iodine.

LABEL, IN PART: (Bottle) "Oil-Acid-Iodine Treatment for Poultry In accordance with formula of Prof. C. E. Lee."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it did not state the purpose or purposes for which the article was intended.

DISPOSITION: June 21, 1951. Default decree of condemnation and destruction.

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM
OFFICIAL OR OWN STANDARDS ***

3507. Adulteration of dl-amphetamine sulfate (powder). U. S. v. 1 Drum
* * * . (F. D. C. No. 30888. Sample Nos. 22871-L, 22873-L.)

LIBEL FILED: April 3, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about January 18, 1951, by the Arenol Chemical Corp., from Long Island City, N. Y.

PRODUCT: 1 drum containing 5½ pounds of *dl-amphetamine sulfate* (powder) at East Newark, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "dl-amphetamine sulfate," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard. The compendium requires that dl-amphetamine sulfate contain equal molecular proportions of dextro-amphetamine sulfate and levo-amphetamine sulfate, whereas the article contained approximately 42 percent of the former and 58 percent of the latter.

DISPOSITION: July 11, 1951. Default decree of condemnation and destruction.

3508. Adulteration and misbranding of tincture of belladonna. U. S. v. 4
Bottles * * * . (F. D. C. No. 31190. Sample No. 4843-L.)

LIBEL FILED: June 11, 1951, District of Massachusetts.

ALLEGED SHIPMENT: On or about April 26, 1951, by Standard Drug Co., Inc., from Newark, N. J.

PRODUCT: 4 1-gallon bottles of *tincture of belladonna* at Worcester, Mass. Analysis showed that the article yielded from each 100 cc. not more than 16.3 mg. of the alkaloids of belladonna leaf.

LABEL, IN PART: "Quality Purity Standard Tincture of Belladonna U. S. P."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Belladonna Tincture," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard since the article yielded from each 100 cc. less than 27 mg. of the alkaloids of belladonna leaf, the minimum permitted by the standard.

Misbranding, Section 502 (a), the label designation "Tincture of Belladonna U. S. P." was false and misleading as applied to an article which was not Tincture of Belladonna U. S. P.

DISPOSITION: July 24, 1951. Default decree of condemnation and destruction.

*See also No. 3503.